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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,556	11/14/2003	Orest W. Blaschuk	100086.415	6364
500	7590	11/01/2006	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104			TELLER, ROY R	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/714,556

Applicant(s)

BLASCHUK ET AL.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 17-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This office action is in response to the election, received 8/31/06. Applicant has elected Group I, claims 1-12 and 16. Claims 13-15 and 17-61 are drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-12 and 16 are pending.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cell adhesion modulating agent that modulates cadherin-mediated cell adhesion; and consists of an amino acid sequence, SEQ ID NO:3 (H-DWVIPP-NH<sub>2</sub>), does not reasonably provide enablement for a cell adhesion modulating agent that modulates cadherin-mediated cell adhesion; and comprises an amino acid sequence Asp/Glu-Trp-Val-Ile/Val/Met-Pro/Ala-Pro (SEQ ID NO:1), but contains no more than 50 consecutive amino acids residues present within the cadherin molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Comprising leaves the claims open for the inclusion of other unspecified, active ingredients even in major amounts. Accordingly, it is asserted that the scope is unduly broad in

Art Unit: 1654

view of the enabling disclosure. See MPEP 2111.03. Blaschuk et al. (USPN 6,031,072) discloses human N-cadherin which encompasses SEQ ID NO:3 of the instant specification. See, i.e., for example, figure 2 of the '072 patent.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to a cell adhesion modulating agent that modulates cadherin-mediated cell adhesion; and comprises an amino acid sequence Asp/Glu-Trp-Val-Ile/Val/Met-Pro/Ala-Pro (SEQ ID NO:1), but contains no more than 50 consecutive amino acids residues present within the cadherin molecule

The unpredictability of the art, the absence of working examples and the quantity of experimentation necessary will be considered here.

The structure/activity relationships of compounds are unpredictable.

Consider, for example, the following:

Avrahami (Biochemistry 40(42) 12591-603, 2001) studied the effects of amino acid substitutions on the antimicrobial activity of amphipathic anti microbial peptides. Many of the compounds prepared lost antibacterial activity as a result of a single amino acid substitution. Although after-the fact rationalizations were provided, the observed structure/activity relationships could not have been predicted *a priori*.

Goldman (FEMS Microbiology Letters 183(2), 209-214, 2000) discloses (sentence bridging pages 210-211) that removal of an amino acid from a vancomycin eliminates activity.

These and other references disclose that there do exist compounds which exhibit no activity, and many of these inactive compounds are structurally analogous to compounds that are active. The key point is that the factors which give rise to activity or inactivity are unknown in the art; and the specification has made no attempt to discuss such factors. Accordingly, one of skill in the art cannot predict activity merely by viewing a structure.

Applicant's example 12, page 117 of the instant specification only gives guidance on the use of SEQ ID NO:3 (H-DWVIPP-NH<sub>2</sub>) and its effects on human ovarian cancer cells. No guidance is present on the effective useage of the numerous permutations present, for example, on pages 21-23 of the instant specification.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a cell adhesion modulating agent that modulates cadherin-mediated cell adhesion; and comprises an amino acid sequence Asp/Glu-Trp-Val-Ile/Val/Met-Pro/Ala-Pro (SEQ ID NO:1), but contains no more than 50 consecutive amino acids residues present within the cadherin molecule; a conservative analogue of SEQ ID NO:1; an antibody or antigen or antigen binding fragment thereof that specifically binds to SEQ ID NO:1; or a peptidomimetic of SEQ ID NO:1. This is vague and indefinite as to the metes and bounds of the invention envisioned by applicant. The invention as recited contains numerous permutations.

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, second paragraph.

### ***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

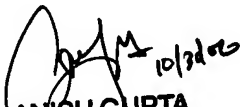
Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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10/26/06

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ANISH GUPTA  
PRIMARY EXAMINER